

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)
)
)
THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.)) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9043

Bartle, J.

April 8, 2013

Linda Potter ("Ms. Potter" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. David A. Potter, Ms. Potter's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In October, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Gregory R. Boxberger, M.D., F.A.C.C. Dr. Boxberger is no stranger to this litigation. According to the Trust, he has attested to at least 74 Green Forms on behalf of claimants seeking Matrix Benefits and has appeared as an expert for claimants in at least 14 Contest and Show Cause proceedings. Based on an echocardiogram dated March 11, 1999, Dr. Boxberger attested in Part II of Ms. Potter's

3. (...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$501,985.⁴

In the report of the claimant's echocardiogram, the reviewing cardiologist, David D. Grove, M.D., Ph.D., F.A.C.P., F.A.C.C., stated that claimant had mild mitral regurgitation. Dr. Grove, however, did not specify a percentage as to claimant's level of mitral regurgitation.⁵ Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In February, 2004, the Trust forwarded the claim for review by Zuyue Wang, M.D., one of its auditing cardiologists. In audit, Dr. Wang concluded that there was no reasonable medical

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

5. Claimant also submitted an echocardiogram report prepared in August, 2002 by Dr. Boxberger based on her March 11, 1999 echocardiogram. In this report, Dr. Boxberger stated that claimant had "moderate mitral regurgitation based on an RJA to LAA ratio of 22%."

basis for Dr. Boxberger's finding that claimant had moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. Dr. Wang explained, "The [mitral regurgitation] should be mild because the RJA/LAA is 10% (1.3/13). The RJA encircled should not include areas of low velocity flow."

Based on Dr. Wang's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Ms. Potter's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted the affidavits of Roger W. Evans, M.D., F.A.C.P., F.A.C.C.,⁷ and Dan A. Francisco, M.D., F.A.C.C. In his declaration, Dr. Evans stated:

b. In reviewing this tape I examined multiple loops and still frames and, in my opinion, the regurgitation shown is not an artifact, phantom jet or backflow.

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Potter's claim.

7. Dr. Evans is also no stranger to this litigation. According to the Trust, he has signed at least 318 Green Forms on behalf of claimant's seeking Matrix Benefits.

c. I have reviewed claimant's echocardiogram of 3/11/99. It shows "moderate" mitral valve regurgitation with a RJA/LAA ratio of approximately 20%. This is best seen in the apical 4-chamber view. In my opinion, the attesting physician had a "reasonable medical basis" to conclude that the echocardiogram tape in question shows "moderate" mitral valve regurgitation

In his declaration, Dr. Francisco stated:

- b. In reviewing this tape I examined multiple loops and still frames and, in my opinion, the regurgitation shown is not an artifact, phantom jet or backflow.
- c. Claimant's echocardiogram of 03/11/99 shows "moderate" mitral valve regurgitation with a RJA/LAA ratio of 24-26%. In my opinion, the attesting physician had a "reasonable medical basis" to conclude that the echocardiogram tape in question shows "moderate" mitral valve regurgitation

Ms. Potter argued, therefore, that there was a reasonable medical basis for her claim because two Board-Certified cardiologists agreed that she had moderate mitral regurgitation. Claimant further asserted that the auditing cardiologist "apparently did not understand the difference between his personal opinion . . . and the 'reasonable medical basis' standard." (Emphasis in original.)

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Wang

submitted a declaration in which she again confirmed that there was no reasonable medical basis for the attesting physician's finding that Ms. Potter had moderate mitral regurgitation. Specifically, Dr. Wang stated:

In connection with my review, I measured Claimant's regurgitant jet area ("RJA") in multiple representative views and found that the largest RJA generously measured was 2.4cm². I also measured the left atrium area ("LAA") in various representative frames and concluded that it consistently measured 15 cm². Accordingly, I conclude that Claimant's true RJA/LAA ratio is no more than 16%.

The Trust then issued a final post-audit determination, again denying Ms. Potter's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO NO. 2807, Audit Rule 18[©]. The Trust then applied to the Court for issuance of an Order to show cause why Ms. Potter's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5240 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 10, 2005, and claimant submitted a sur-reply on November 29, 2005. Under the

Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, M.D., to review the documents submitted by the Trust and claimant and to prepare a report for the Court. The Show Cause Record and Technical Advisor Report are now before the Court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Potter reasserts the arguments made in contest; namely, that the opinions of Dr. Boxberger, Dr. Evans, and Dr. Francisco provide a reasonable medical basis for finding that claimant had moderate mitral regurgitation. In addition, claimant contends that the concept of inter-reader variability accounts for the difference between the opinions of the attesting physician and the auditing cardiologist. According to claimant, there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, Ms. Potter contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA ratio by an attesting physician is medically reasonable.

In response, the Trust argues that claimant's physicians do not establish a reasonable medical basis for Dr. Boxberger's findings because they simply make conclusory statements rather than respond to Dr. Wang's specific findings. The Trust also notes that neither claimant nor her physicians address the original echocardiogram report of Dr. Grove, who concluded that the level of claimant's mitral regurgitation was mild. Finally, the Trust contends that inter-reader variability does not establish a reasonable medical basis for the claim

because Dr. Wang specifically found that there was no reasonable medical basis for the findings of Dr. Boxberger.

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's representation that claimant had moderate mitral regurgitation. Specifically, Dr. Burke stated:

My impression of the March 11, 1999 echocardiogram, by visual inspection, is that the mitral regurgitation appears mild. There are no color flow Doppler images in the apical two chamber, apical three chamber, or subcostal views to assess the severity of mitral regurgitation.

Using beats in the apical four chamber view, I measured the RJA/LAA ratio to range from 9 to 22%. The average RJA/LAA ratio in this view was 15%. In only one frame was I able to obtain an RJA/LAA ratio greater than 20%. I thought that this one frame was not representative of the level of mitral regurgitation throughout the entire study. The measured beats represent mild regurgitation.

I have no obvious explanation as to the variability seen in the RJA/LAA ratio.

Even accounting for inter-reader variability in the assessment of mitral regurgitation, an echocardiographer could not reasonably conclude that the echocardiogram dated March 11, 1999 indicates that this Claimant has more than mild mitral regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately refute the findings of the auditing cardiologist and

Technical Advisor. Claimant does not rebut Dr. Wang's observation that Ms. Potter had mild mitral regurgitation and that "[t]he RJA encircled should not include areas of low velocity flow."⁹ In addition, claimant does not challenge Dr. Burke's explanation that claimant had only mild mitral regurgitation and that the only frame resulting in an RJA/LAA ratio greater than 20% "was not representative of the level of mitral regurgitation through the entire study."¹⁰ Neither claimant nor her physicians identified any particular error in the conclusion of the auditing cardiologist or the Technical Advisor. They also did not provide and explanation for the reviewing cardiologist's determination that claimant's echocardiogram demonstrated only mild mitral regurgitation. Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

We also reject claimant's argument that the opinions of Dr. Evans and Dr. Francisco provide a reasonable medical basis for Dr. Boxberger's representation that claimant had moderate mitral regurgitation. Dr. Evans and Dr. Francisco concluded that

9. For this reason as well, we reject claimant's argument that Dr. Wang substituted her personal opinion for that of the attesting physician.

10. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

there was a reasonable medical basis for Dr. Boxberger's representation of moderate mitral regurgitation based on an RJA/LAA ratio of approximately 20% and "24-26%," respectively. Although Dr. Burke observed that claimant's echocardiogram demonstrated one frame with an RJA/LAA ratio greater than 20%, he concluded that this one frame was not representative of the level of mitral regurgitation throughout claimant's echocardiogram. We previously have rejected attempts by claimants to rely on a single frame from an echocardiographic study that was not representative of the level of mitral regurgitation present on the entire study. See, e.g., PTO No. 8659 at 10 (Aug. 8, 2011). As we explained, "'[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of regurgitation are representative of the level of regurgitation throughout an echocardiogram.'" Id. (quoting PTO No. 6997 at 11 (Feb. 26, 2007)); see also In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 543 F.3d 179, 187 (3d Cir. 2008). "'To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.'" Id. (quoting PTO No. 6997 at 11).

Finally, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the

attesting physician's representation that she had moderate mitral regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the auditing cardiologist determined that claimant's echocardiogram demonstrated an RJA/LAA ratio of 10% and the Technical Advisor determined claimant's echocardiogram demonstrated an average RJA/LAA ratio of 15%. Adopting claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation by $\pm 15\%$ would allow a claimant to recover benefits with an RJA/LAA ratio as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.¹¹

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Potter's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

11. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement, "Even accounting for inter-reader variability in the assessment of mitral regurgitation, an echocardiographer could not reasonably conclude that the echocardiogram dated March 11, 1999 indicates that this Claimant has more than mild mitral regurgitation."